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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,797	12/04/2001	John David Fraser	55503-002001	9884

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
08/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/006,797	FRASER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/22/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,10,11,13,15-18,21-26,28-38 and 40-45* is/are pending in the application.

4a) Of the above claim(s) *17,18,21-26 and 28-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6, 10-11, 13, 15-16, and 40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 5/22/09, are acknowledged.
Claims 2, 10, 21, 26, and 30-31 have been amended.
Claims 2-6, 10-11, 13, 15-18, 21-26, 28-38, and 40-45 are pending.

2. Claims 17-18, 21-26, and 28-38 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Upon reconsideration, the examination is extended to include the other SPE-C mutants in claims 40-45.
Claims 2-6, 10-11, 13, 15-16, 40-45 are being acted upon.

3. In view of Applicant's amendment to the claims, the previous grounds of rejection are withdrawn.

4. The following are new grounds of rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of specific amino acid residues of SPE-C in the absence of a SEQ ID NO. SPE-C exists as different isoforms, alleles, and fragments (see WO 98/24910, page 7, in particular). Therefore a particular residue (for example residue 15) would not likely be the same in all SPE-C polypeptides. Therefore, in the absence of a SEQ ID NO, the metes and bounds of the claims directed to specific residues of a polypeptide cannot be determined.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-6, 10-11, 13, 15-16, 40-41, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/31483, in view of WO 98/24910.

WO 95/31483 teaches a polypeptide conjugate comprising a targeting portion that binds to MHC class II molecules, and an antigenic portion that is suitable for processing and presentation to the immune system. WO 95/31483 teaches that binding of the targeting polypeptide to MHC molecules results in internalized into antigen presenting cells, processing of the conjugated antigenic peptide, and induction a strong immune response against the delivered antigens without the use of an adjuvant (see page 6 in particular). WO 95/31483 teaches that after internalization the antigenic peptide can be digested, processed and transported to the cell surface on MHC molecules (i.e. the peptide portion is "reversibly" coupled to the targeting portion, see page 4 in particular). WO 95/31483 also teaches the conjugated polypeptides as part of a vaccine (i.e. a composition including a pharmaceutically acceptable carrier, see page 3, in particular).

WO 95/31483 does not teach using a mutated superantigen as the protein that targets MHC class II molecules.

WO 98/24910 teaches that superantigens such as SPE-C function to bind to MHC class II molecules (see page 7, in particular). WO 98/24910 teaches SPE-C mutants suitable for use as a vaccine, wherein the SPE-C is mutated in TCR binding residues, such that the mutants are less toxic and display less T cell mitogenicity (i.e. the TCR binding site has been "deleted", see page 18, Table 3, and page 37). WO 98/24910 teaches a particular mutant comprising the Y15A mutation (see page 37, in particular). Additionally, WO 98/24910 teaches the residues of SPE-C that are critical in MHC class II binding and TCR binding (see Table II and III). Particularly, WO 98/24910 teaches that R181 is a residue involved in TCR interaction. WO 98/24910 also teaches that SPE-C can be mutated by introducing any of the other 19 amino acids (i.e. including residues Q, see Table III and page 10 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was use an MHC binding SPE-C superantigen as taught by WO 98/24910, as the MHC targeting portion in the conjugate polypeptides taught by WO 95/31483. The ordinary artisan at the time the invention was made would have been motivated to particularly to use a mutated superantigens containing mutations in the T cell receptor binding sites such as the Y15A mutant, since WO 98/24910 teaches that said TCR binding site mutated superantigens are less toxic in vivo. Furthermore, the ordinary artisan would have a reasonable expectation of success in using the MHC binding mutated SPE-C superantigen, since WO 95/31483 teaches that polypeptides bound to MHC are normally internalized, leading to the processing and presentation of said polypeptides. Additionally, it would have been obvious to use the Y15A mutant in combination with a mutation in any other known TCR binding residue that is not involved in MHC binding (such as R181, as taught by WO 95/31483). Choosing among the known amino acids for substitution of the R181 residue would involve choosing among a finite number of predictable options which could be pursued with a reasonable expectation of success. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is

likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. V. Telefex Inc* 82 USPQ2d 1385).

7. No claim is allowed. Claims 42 and 43 are free of the art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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